FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 01/31/2006

GUIDANCE DOCUMENT FOR REPORT OF TRANSFER OF SELECT AGENTS AND TOXINS

INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Public Law 107-188; June 12, 2002), requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (7 CFR 331 and 9 CFR 121).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection. This form (APHIS/CDC Form 2) is designed to assist entities in complying with this legal obligation.

A registered entity is required by regulation (7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16) to file this form with either APHIS or CDC and obtain approval prior to transfer of a select agent or toxin. The Sender's Responsible Official (RO) or facility director must submit the form for authorization of the transfer to either APHIS (facsimile: 301-734-3652) or CDC (facsimile: 404-498-2265). A copy of each completed form must be kept for three years.

INSTRUCTIONS

The purpose of this form is to provide a method for the documentation of the transfer of a select agent or toxin. The form must be completed for each transfer of select agents or toxins.

Prior to transferring a select agent or toxin:

(A) Submission of the form to APHIS or CDC.

1. **Recipient:** Completes Section A and blocks 30 and 37. The recipient's RO then sends the form to the sender.
2. **Sender:** Completes Section B and blocks 31-36. Characterization of agent should include data such as strain designation, GenBank Accession number, publication citation, molecular characterization data, etc. (provide additional information on attached sheet if needed). The sender's RO or entity director transmits the form via facsimile to APHIS (FAX: 301-734-3652) or CDC (FAX: 404-498-2265).

NOTE:

1. Information provided for this form should match the information submitted for the entity's certificate of registration.
2. Clinical and diagnostic laboratories that transfer select agents and toxins after identification (See 7 CFR 331, 9 CFR 121, and 42 CFR 73) are required to complete and submit this form for approval prior to transferring the select agent or toxin to a registered entity.
3. The transfer of select agents may require the intended recipient to obtain a USDA permit prior to the interstate movement of the agent (See 7 CFR Part 330 and 9 CFR Part 122). The USDA permit applications are available on the web at www.aphis.usda.gov. For questions concerning the USDA permits, please call 301-734-5960.
4. Importation of select agents may require the intended recipient to obtain a valid USDA and/or PHS permit prior to the importation event (See 7 CFR Part 330.200, 9 CFR Part 122.2, and 42 CFR Part 71.54) The application and instructions for obtaining USDA import permits is available through the APHIS website at: http://www.aphis.usda.gov/vs/ncie/ or PPQ website at: http://www.aphis.usda.gov/ppq/permits/ or by calling 301-734-5960. The application and instructions for obtaining PHS import permits is available through the CDC website at: http://www.cdc.gov/od/ohs/biosfty/imprtper.htm or by calling 404-498-2260.
    a. After obtaining the appropriate permits, the APHIS/CDC Form 2 must be completed. An authorization for approval from APHIS or CDC must be received prior to the shipment of the select agents or toxins under the permit.
    b. The Recipient Responsible Official (RO) must complete APHIS/CDC Form 2:
        (1) Completes Sections A and B as instructed.
        (2) Completes Sections C and D for sender, placing the "APHIS Permit Number or PHS Permit Number" in block 3 of the form.
        (3) Transmits the form via facsimile to CDC (FAX: 404-498-2265) or APHIS (FAX: 301-734-3652).

(B) Issuance of approval authorization number. APHIS or CDC will FAX the form back to the sender and/or recipient with an approval authorization number after verification of the information on the form. The approval authorization number will be valid for only 30 days after issuance. If the sender has a suspicion that the agent may not be used for the requested purpose, then the sender should consult with APHIS or CDC prior to the transfer.

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Transfer after authorization of transfer:

(A) Shipment of the select agent or toxin to the recipient.

Sender: Must ship the material to the recipient only after the sender has received the approval authorization number from APHIS or CDC. The sender completes blocks 38-40. Select agents and toxins must be packaged, labeled, and shipped in accordance with all federal regulations (e.g., 42 CFR 72, 49 CFR 100-180, 9 CFR 121, and 7 CFR 331) and international regulations. It is highly recommended that the sender utilize a method for tracking the movement of the select agents and toxins being shipped.

(B) Transmittal of the form to APHIS or CDC.

Recipient: Upon receipt of the shipment, the recipient's RO must complete blocks 41 and 42 and FAX or mail the form to both the sender's RO and APHIS or CDC **within 2 business days of receipt**. The recipient's RO must immediately report to APHIS or CDC and complete APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) if the select agent or toxin has not been received within 48 hours after the expected delivery time, the package received containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred, or the amount received differs from that indicated by the sender in Section C.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or the CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5960 or CDC at (404) 498-2255.

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REPORT OF TRANSFER OF SELECT AGENTS AND TOXINS

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. This report must be signed by the Responsible Official and submitted to Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737 (FAX: 301-734-3652) or Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333 (FAX: 404-498-2265).

FOR APHIS/CDC USE ONLY

APHIS/CDC AUTHORIZATION NUMBER: _____ DATE: _____ INI:_____ EXP DATE: _____

SECTION A – RECIPIENT (REQUESTOR) INFORMATION

1. Entity name	2. Entity registration number	3. ☐ APHIS Permit # and/or US PHS#:

4. Recipient name (Authorized Personnel) (Last, First, Middle) Print: Signature:	5. Date	6. Phone	7. FAX
8. Principal investigator (Principal Investigator, if different from line above) Print: Signature:	9. Date	10. Phone	11. FAX
12. Responsible Official name (Last, First, Middle) Print: Signature:	13. Date	14. Phone	15. FAX

SECTION B – SENDER (TRANSFEROR) INFORMATION

16. Entity name	17. ☐ Entity registration number: _____ ☐ Clinical/diagnostic laboratory ☐ Other: _____

18. Sender name (Last, First, Middle) Print: Signature:	19. Date	20. Phone	21. FAX
22. Principal investigator (Principal Investigator, if different from line above) Print: Signature:	23. Date	24. Phone	25. FAX
26. Responsible Official name (Last, First, Middle) Print: Signature:	27. Date	28. Phone	29. FAX

SECTION C – LIST OF SELECT AGENTS AND TOXINS SHIPPED (attach additional sheets if necessary)

	RECIPIENT	SENDER					
	30. Select agent or toxin	31. Characterization of agent or toxin (*see instructions*)	32. Number of vials	33. Form (e.g., powder/liquid/ slant)	34. Vol or wt per vial (e.g., ml, mg)	35. Total quantity	36. Concentration/ vial (e.g., 10^8 cfu/ml)
a							
b							
c							
d							

37. Proposed Use: ☐ Research ☐ Diagnostics ☐ Production ☐ Other (explain):

SECTION D – SHIPPING INFORMATION (attach additional sheets if necessary)

38. Number of primary receptacles per outer package____ Number of outer packages _____ Carrier waybill (tracking) #(s):

39. Sender (Responsible Official or Facility Director) verifies select agents or toxins listed in Section C were shipped: Print: Signature:	40. Date shipped:
41. Recipient (Responsible Official) verifies select agents or toxins listed in Section C were received: Print: Signature:	42. Date received:

Public reporting burden: Public reporting burden of this collection of information is estimated to average 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

Penalties: Knowingly providing false statements on any part of this form or its attachments will subject the offender to fines of up to $250,000 ($500,000 for organizations), imprisonment for up to 5 years or both (18 USC Section 1001). Failure to maintain records constitutes a 1 year misdemeanor (42 USC Section 271).